| Substitute for form 1449/PTO (Revised 04/2003) | | | | Complete if Known | | |
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| | | | | Application Number | 10/750,076 | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | First Named Inventor Wolfe | | |
| | | | | Group Art Unit | Not yet assigned | |
| (Use as many sheets as necessary) | | Examiner Name | Not yet assigned | | | |
| heet | 11 | of | 3 | Attorney Docket Number | PP16022.017 (35784/271881) | |
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|---|--------------------|-------------|--|--------------------------------|--|---|
| | Examiner Initials* | Cite No. | Document Number Number - Kind Code (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear |
| | ВН | 1 | US-4,462,940 | 07-31-1984 | Hanisch et al. | |
| | _ | 2 | US-4,816,440 | 03-28-1989 | Thomson, J.W. | |
| ļ | | 3 | US-4,894,330 | 01-16-1990 | Hershenson et al. | |
| ļ | | 4 | US-4,931,543 | 06-05-1990 | Halenbeck et al. | |
| ļ | | 5 | US-4,992,271 | 02-12-1991 | Fernandes et al. | |
| ļ | | 6 | US-5,162,507 | 11-10-1992 | Wolfe et al. | |
| ļ | \/ | 7 | US-5,643,566 | 07-01-1997 | Hanisch et al. | |
| L | <u> </u> | 8 | US-5,702,699 | 12-30-1997 | Hanisch et al. | |

| | | FOREI | GN PATENT D | OCUMENTS | | |
|----------------------|-------------|--|--------------------------------|---|--|--|
| Examiner Initials | Cite No. | Foreign_Patent Document Country Code - Number Kind Code (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | English Language Translation Attached |
| BH | 9 | EP 0 217 645 B1 | 04-08-1987 | Cetus Corporation | | |
| | 10 | EP 0 270 799 B1 | 06-15-1988 | Cetus Oncology Corporation | | |
| | 11 | EP 0 360 937 | 04-04-1990 | Cetus Corporation | | |
| | 12 | KR 9 306 706 B | 07-23-1993 | Lucky Ltd. | | |
| | 13 | EP 0 215 658 B1 | 06-01-1994 | Cetus Oncology Corporation | | |
| | 14 | WO 95/31479 | 11-23-1995 | Inhale Therapeutic Systems, Inc. | | |
| | 15 | WO 98/27211 | 06-25-1998 | Universidade Federal De Minas Gerais | | |
| | 16 | WO 02/080976 | 10-17-2002 | Chiron Corporation | <u> </u> | |

| Examiner | /Bruce Hissong/ | Date | 09/13/2006 |
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| Signature | • | Considered | |

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| S | Substitute for form 1449/PTO | | | | Complete if Known | | |
|-------------------|--|------------|---------|--------------------|------------------------|----------------------------|--|
| (Revised 04/2003) | | | | Application Number | 10/750,076 | | |
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| | INFORMATION DISCLOSURE | | | | First Named Inventor | Wolfe | |
| | STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Group Art Unit | Not yet assigned | |
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|---------------------------------------|-------------|---|--|
| 0 | | OTHER DOCUMENTS | |
| Resonance Fritials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | English Language Translation Attached |
| ВН | 17 | AHN, J., et al., "Investigation of Refolding Condition for Pseudomonas Fluorescens Lipase by Response Surface Methodology," J. Biotechnol., 1997, pp. 151-160, Vol. 54(3). | |
| | 18 | BAM, N., et al., "Molten Globule Intermediate of Recombinant Human Growth Hormone: Stabilization with Surfactants," Biotechnol. Prog., 1996, pp. 801-809, Vol. 12(6). | |
| | 19 | CARPENTER, J., and J.H. CROWE, "The Mechanism of Cryoprotection of Proteins by Solutes," <i>Cryobiology</i> , 1988, pp. 244-255, Vol. 25(3). | |
| | 20 | CHARMAN, S., et al., "Techniques for Assessing the Effects of Pharmaceutical Excipients on the Aggregation of Porcine Growth Hormone," <i>Pharm. Res.</i> , 1993, pp. 954-962, Vol. 10(7). | |
| | 21 | CLELAND, J., et al., "Polyethylene Glycol Enhanced Protein Refolding," Biotechnology, 1992, pp. 1013-1019, Vol. 10(9). | |
| | 22 | DAUGHERTY, D., et al., "Artificial Chaperone-Assisted Refolding of Citrate Synthase," J. Biol. Chem., 1998, pp. 33961-33971, Vol. 273(51). | |
| | 23 | DRYDEN, D., and M.P. WEIR, "Evidence for an Acid-Induced Molten-Globule State in Interleukin-2; A Fluorenscence and Circular Dichroism Study," <i>Bioichim. Biophys. Acta</i> , 1991, pp. 94-100, Vol. 1078(1). | · |
| | 24 | EDY, V., et al., "Stabilisation of Mouse and Human Interferons by Acid pH Against Inactivation Due to Shaking and Guanidine Hydrochloride," <i>Proc. Soc. Exp. Biol. Med.</i> , 1974, pp. 249-253, Vol. 146(1). | |
| | 25 | EDY, V., et al., "Stable and Unstable Forms of Human Fibroblast Interferon," Infect. Immun., 1977, pp. 445-448, Vol. 16(2). | |
| | 26 | GAUTHIER, M., and P.A. PATSTON, "Reactivation of C1-Inhibitor Polymers by Denaturation and Gel-Filtration Chromatography," <i>Anal. Biochem.</i> , 1997, pp. 228-233, Vol. 248(2). | |
| | 27 | HOURY, W., et al., "The Nature of the Initial Step in the Conformational Folding of Disulphide- Intact Ribonuclease A," Nat. Struct. Biol., 1995, pp. 495-503, Vol. 2(6) | |
| V | 28 | JARIWALLA, R., et al., "The Reactivation of Human Interferons by Guanidine Thiocyanate," Experientia, 1980, pp. 1390-1391, Vol. 36(12). | |

| Examiner | /Bruce Hissong/ | Date | 09/13/2006 | 1 |
|-----------|-----------------|------------|------------|---|
| Signature | | Considered | 03/13/2000 | ĺ |

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Substitute for form 1449/PTO (Revised 04/2003) | | | | Complete if Known | | |
|---|------------------------|-------------|-------------------|------------------------|----------------------------|--|
| | | | | Application Number | 10/750,076 | |
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| (Use as many sheets as necessary) | | | | Examiner Name | Not yet assigned | |
| Sheet | 3 | of | 3 | Attorney Docket Number | PP16022.017 (35784/271881) | |

| | | OTHER DOCUMENTS | |
|--------|-------------|---|--|
| | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | English Language Translation Attached |
| вн | 29 | KENDRICK, B., et al., "Quantitation of the Area of Overlap Between Second-Derivative Amide I Infrared Spectra to Determine the Structural Similarity of a Protein in Different States," J. Pharm. Sci., 1996, pp. 155-158, Vol. 85(2). | |
| 30 | | LEE, J.K., et al., "Purification of Human Interferon-β from Recombinant E. coli," Korean Biochemical Journal, 1990, pp. 166-171, Vol. 23(2). | |
| | 31 | MUZAMMIL, S., et al., "Molten Globule-Like State of Human Serum Albumin at Low pH," Eur. J. Biochem., 1999, pp. 26-32, Vol. 266(1). | |
| | 32 | PEPINSKY, R.B., "Selective Precipitation of Proteins from Guanidine Hydrochloride-Containing Solutions with Ethanol," <i>Analytical Biochemistry</i> , 1991, pp. 177-181, Vol. 195. | |
| | 33 | ROZEMA, D., and S.H. GELLMAN, "Artificial Chaperone-Assisted Refolding of Denatured-Reduced Lysozyme: Modulation of the Competition Between Renaturation and Aggregation," Biochemistry, 1996, pp. 15760-15771, Vol. 35(49). | |
| | 34 | ROZEMA, D., and S.H. GELLMAN, "Artificial Chaperone-Assisted Refolding of Carbonic Anhydrase B," <i>J. Biol. Chem.</i> , 1996, pp. 3478-3487, Vol. 271(7). | |
| | 35 | RUSSELL-HARDE, D., et al., "The Use of Zwittergent 3-14 in the Purification of Recombinant Human Interferon-β Ser ¹⁷ (Betaseron)," Journal of Interferon and Cytokine Research, 1995, pp. 31-37, Vol. 15(1). | |
| | 36 | TODHUNTER, R., et al., "Structure of Equine Type I and Type II Collagens," Am. J. Vet. Res., 1994, pp. 425-431, Vol. 55(3). | |
| | 37 | VAN OSS, C.J., "On the Mechanism of the Cold Ethanol Precipitation Method of Plasma Protein Fractionation," <i>Journal of Protein Chemistry</i> , 1989, pp. 661-668, Vol. 8(5). | |
| | 38 | WEIR, M., et al., "Micropreparative Purification of Recombinant Human Interleukin-2," J. Chromatogr., 1987, pp. 209-215, Vol. 396. | |
| Ψ | 39 | XIE, Y. and D. B. WETLAUFER, "Control of Aggregation in Protein Refolding: The Temperature-Leap Tactic," <i>Protein Sci.</i> , 1996, pp. 517-523, Vol. 5(3). | |

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| Examiner | /Bruce Hissong/ | Date | 09/13/2006 |
| Signature | , 50 acc accord, | Considered | |

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.